



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:  
Application No.:  
Filed:  
For:

Marsha A. Moses, Li Yan

09/977,878

10/15/01

Group No.: 1642

Examiner: Karen A. Canella

NON-INVASIVE ENZYME SCREEN FOR TISSUE REMODELLING  
ASSOCIATED CONDITIONS

CERTIFICATE OF MAILING (37 C.F.R. SECTION 1.8(a))

I hereby certify that this paper (along with any paper referred to as being attached or enclosed) is being deposited with the United States Postal Service on the date shown below with sufficient postage as first class mail in an envelope addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450

Date

1/23/2004

Nicole M. Gignac

(type or print name of person mailing paper)

*Nicole M. Gignac*  
Signature of person mailing paper

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir/Madam:

**INFORMATION DISCLOSURE STATEMENT**

In accordance with the provisions of 37 C.F.R. §1.56, 1.97, and 1.98, Applicants wish to bring to the Examiner's attention the following references, References AA, BA, and CA - CI, cited in the attached Form PTO-1449.

01/28/2004 HGUENA1 00000097 09977878

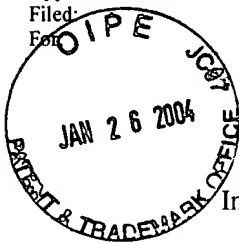
01 FC:1806

180.00 OP

In re application of:  
Application No.:  
Filed:  
For:

Marsha A. Moses, Li Yan  
09/977,878  
10/15/01

Group No.: 1642  
Examiner: Karen A. Canella  
NON-INVASIVE ENZYME SCREEN FOR TISSUE REMODELLING ASSOCIATED CONDITIONS



### REMARKS

In accordance with the provisions of 37 C.F.R. §1.97, this statement is being filed:

- (1) within three (3) months of the Filing Date or **before the mailing date of the First Office Action** on the merits; or
- (2) within three months of the mailing date of the PCT International Search Report; or
- X (3) after the period defined in (1) but before the mailing date of a **Final Rejection or Notice of Allowance**, and the requisite Certification or fee under Rule 1.17(p), namely **\$180.00**, is included herein; or
- (4) after the mailing date of a **Final Rejection or Notice of Allowance** but before the payment of the **Issue Fee**, and the requisite Certification, petition, and petition fee are included herein.

X A copy of the International Search Report is enclosed herewith.

It is respectfully requested that each of the documents shown on the attached form(s) PTO-1449 be made of record in this application.

Copies of these documents (CHECK ONE):

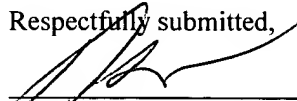
X are enclosed herewith; or  
— have been cited in the parent application, and are thus not being resubmitted herein.

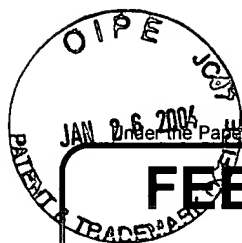
### FEE AUTHORIZATION

The Commissioner is authorized to charge fee deficiencies or credit overpayments associated with this submission to the NIXON PEABODY LLP Deposit Account No. 50-0850.

Date: 1/23/04

Respectfully submitted,

  
David S. Resnick (Reg. No. 34,235)  
NIXON PEABODY LLP  
101 Federal Street  
Boston, MA 02110  
(617) 345-6057



# FEE TRANSMITTAL for FY 2004

Effective 10/01/2003. Patent fees are subject to annual revision.

☒ Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT (\$ ) 180.00

## Complete if Known

Application Number	09/997,878
Filing Date	10/15/2001
First Named Inventor	M.A. Moses
Examiner Name	K.A. Canella
Art Unit	1642
Attorney Docket No.	701039-054701

## METHOD OF PAYMENT (check all that apply)

☒ Check ☐ Credit card ☐ Money Order ☐ Other ☐ None

☒ Deposit Account:

Deposit  
Account  
Number  
Deposit  
Account  
Name

50-0850

NIXON PEABODY LLP

The Director is authorized to: (check all that apply)

☐ Charge fee(s) indicated below ☐ Credit any overpayments

☒ Charge any additional fee(s) or any underpayment of fee(s)

☐ Charge fee(s) indicated below, except for the filing fee to the above-identified deposit account.

## FEE CALCULATION

### 1. BASIC FILING FEE

Large Entity		Small Entity		Fee Description	Fee Paid
Fee Code	Fee (\$)	Fee Code	Fee (\$)		
1001	770	2001	385	Utility filing fee	
1002	340	2002	170	Design filing fee	
1003	530	2003	265	Plant filing fee	
1004	770	2004	385	Reissue filing fee	
1005	160	2005	80	Provisional filing fee	

SUBTOTAL (1) (\$ )

### 2. EXTRA CLAIM FEES FOR UTILITY AND REISSUE

	Extra Claims	Fee from below	Fee Paid
Total Claims	20** =	X	
Independent Claims	3** =	X	
Multiple Dependent			

Large Entity		Small Entity		Fee Description
Fee Code	Fee (\$)	Fee Code	Fee (\$)	
1202	18	2202	9	Claims in excess of 20
1201	86	2201	43	Independent claims in excess of 3
1203	290	2203	145	Multiple dependent claim, if not paid
1204	86	2204	43	** Reissue independent claims over original patent
1205	18	2205	9	** Reissue claims in excess of 20 and over original patent

SUBTOTAL (2) (\$ )

\*\*or number previously paid, if greater; For Reissues, see above

## FEE CALCULATION (continued)

### 3. ADDITIONAL FEES

Large Entity		Small Entity		Fee Description	Fee Paid
Fee Code	Fee (\$)	Fee Code	Fee (\$)		
1051	130	2051	65	Surcharge - late filing fee or oath	
1052	50	2052	25	Surcharge - late provisional filing fee or cover sheet	
1053	130	1053	130	Non-English specification	
1812	2,520	1812	2,520	For filing a request for <i>ex parte</i> reexamination	
1804	920*	1804	920*	Requesting publication of SIR prior to Examiner action	
1805	1,840*	1805	1,840*	Requesting publication of SIR after Examiner action	
1251	110	2251	55	Extension for reply within first month	
1252	420	2252	210	Extension for reply within second month	
1253	950	2253	475	Extension for reply within third month	
1254	1,480	2254	740	Extension for reply within fourth month	
1255	2,010	2255	1,005	Extension for reply within fifth month	
1401	330	2401	165	Notice of Appeal	
1402	330	2402	165	Filing brief in support of an appeal	
1403	290	2403	145	Request for oral hearing	
1451	1,510	1451	1,510	Petition to institute a public use proceeding	
1452	110	2452	55	Petition to revive - unavoidable	
1453	1,330	2453	665	Petition to revive - unintentional	
1501	1,330	2501	665	Utility issue fee (or reissue)	
1502	480	2502	240	Design issue fee	
1503	640	2503	320	Plant issue fee	
1460	130	1460	130	Petitions to the Commissioner	
1807	50	1807	50	Processing fee under 37 CFR 1.17(q)	
1806	180	1806	180	Submission of Information Disclosure Stmt	180.00
8021	40	8021	40	Recording each patent assignment per property (times number of properties)	
1809	770	2809	385	Filing a submission after final rejection (37 CFR 1.129(a))	
1810	770	2810	385	For each additional invention to be examined (37 CFR 1.129(b))	
1801	770	2801	385	Request for Continued Examination (RCE)	
1802	900	1802	900	Request for expedited examination of a design application	

Other fee (specify)

\*Reduced by Basic Filing Fee Paid

SUBTOTAL (3) (\$ ) 180.00

## SUBMITTED BY

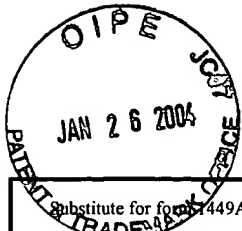
Name (Print/Type)	David S. Resnick	Registration No. (Attorney/Agent)	34,235	Telephone	(617) 345-6057
Signature		Date	1/23/04		

**WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.**

This collection of information is required by 37 CFR 1.17 and 1.27. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.





Substitute for form 449A/PTO <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> (use as many sheets as necessary)				<b>Complete if Known</b>	
				Application Number	09/977,878
				Filing Date	10/15/2001
				First Named Inventor	Marsha A. Moses
				Art Unit	1642
Examiner Name	Karen A. Canella				
Sheet	2	of	2	Attorney Docket Number	701039-054701

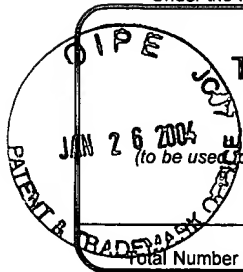
OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS				
Examiner Initials <sup>*</sup>	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>	
	CA	Baker, T. <i>et al.</i> "Serum metalloproteinases and their inhibitors: markers for malignant potential." <i>Br J Cancer</i> . 1994 Sep.; 70(3):506-12.		
	CB	Garbisa, S. <i>et al.</i> "Correlation of serum metalloproteinase levels with lung cancer metastasis and response to therapy." <i>Cancer Res</i> . 1992 Aug 15; 52(16):4548-9.		
	CC	Kleiner, D.E. <i>et al.</i> "Matrix metalloproteinases and metastasis." <i>Cancer Chemother. Pharmacol</i> . 1999; 43 Suppl:S42-51.		
	CD	Lochter, A. <i>et al.</i> "The significance of matrix metalloproteinases during early stages of tumor progression." <i>Ann N Y Acad Sci</i> . 1998 Oct 23; 857:180-93.		
	CE	Monier, F. <i>et al.</i> "Gelatinase isoforms in urine from bladder cancer patients" <i>Clin. Chim. Acta</i> . 2000 Sep; 299 (1-2):11-23.		
	CF	Moses, M. <i>et al.</i> "Increased incidence of matrix metalloproteinases in urine of cancer patients" <i>Cancer Res</i> . 1998 Apr 1; 58(7): 1395-9.		
	CG	Nakajima, M. <i>et al.</i> "Serum and plasma M(r) 92,000 progelatinase levels correlate with spontaneous metastasis of rat 13762 NF mammary adenocarcinoma." <i>Cancer Res</i> . 1993 Dec 1; 53(23):5802-7.		
	CH	Yan, Li, <i>et al.</i> "The high molecular weight urinary matrix metalloproteinase (MMP) activity is a complex of gelatinase B/MMP-9 and neutrophil gelatinase-associated lipocalin (NGAL). Modulation of MMP-9 activity by NGAL" <i>J Biol Chem</i> . 2001 Oct 5;276(40):37258-65.		
	CI	Zucker, S. <i>et al.</i> "Plasma assay of matrix metalloproteinases (MMPs) and MMP inhibitor complexes in cancer. Potential use in predicting metastasis and monitoring treatment." <i>Ann NY Acad. Sci</i> . 1994 Sep 6; 732:248-62.		

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

\* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

**TRANSMITTAL  
FORM**

(to be used for all correspondence after initial filing)

Application Number	09/977,878
Filing Date	10/15/2001
First Named Inventor	M.A. Moses
Art Unit	1642
Examiner Name	K.A. Canella
Attorney Docket Number	701039-054701

Total Number of Pages in This Submission

**ENCLOSURES (Check all that apply)**

<input type="checkbox"/> Fee Transmittal Form <input type="checkbox"/> Fee Attached <input type="checkbox"/> Amendment/Reply <input type="checkbox"/> After Final <input type="checkbox"/> Affidavits/declaration(s) <input type="checkbox"/> Extension of Time Request <input type="checkbox"/> Express Abandonment Request <input checked="" type="checkbox"/> Information Disclosure Statement <input type="checkbox"/> Certified Copy of Priority Document(s) <input type="checkbox"/> Response to Missing Parts/Incomplete Application <input type="checkbox"/> Response to Missing Parts under 37 CFR 1.52 or 1.53	<input type="checkbox"/> Drawing(s) <input type="checkbox"/> Licensing-related Papers <input type="checkbox"/> Petition <input type="checkbox"/> Petition to Convert to a Provisional Application <input type="checkbox"/> Power of Attorney, Revocation <input checked="" type="checkbox"/> Change of Correspondence Address <input type="checkbox"/> Terminal Disclaimer <input type="checkbox"/> Request for Refund <input type="checkbox"/> CD, Number of CD(s) _____	<input type="checkbox"/> After Allowance Communication to Group <input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences <input type="checkbox"/> Appeal Communication to Group (Appeal Notice, Brief, Reply Brief) <input type="checkbox"/> Proprietary Information <input type="checkbox"/> Status Letter <input checked="" type="checkbox"/> Other Enclosure(s) (please identify below): Form 1449; References AA, BA and CA - CI; Certificate of Mailing; Return Receipt Postcard.
<b>Remarks</b> The Commissioner is authorized to charge deficiencies associated with this submission to the NIXON PEABODY LLP Deposit Account No. 50-0850.		

**SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT**

Firm or Individual name	David S. Resnick (Reg. No. 34,235) NIXON PEABODY LLP, 101 Federal Street, Boston, MA 02110		
Signature	<i>[Signature]</i>		
Date	1/23/04		

**CERTIFICATE OF TRANSMISSION/MAILING**

I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below. Washington, DC 20231 on this date:

Typed or printed name	Nicole M. Gignac		
Signature	<i>Nicole M. Gignac</i>	Date	1/23/2004

This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.



Attorney Docket No. 701039-054701

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Marsha A. Moses, Li Yan  
Application No.: 09/977,878 Group No.: 1642  
Filed: 10/15/01 Examiner: Karen A. Canella  
For: NON-INVASIVE ENZYME SCREEN FOR TISSUE REMODELLING  
ASSOCIATED CONDITIONS

CERTIFICATE OF MAILING/TRANSMISSION (37 C.F.R. § 1.8(a) and 1.10)

I hereby certify that this correspondence:

1. Transmittal Form (1 pg.);
2. Information Disclosure Statement (2 pp.);
3. Form 1449 (2 pp.);
4. References AA, BA, and CA - CI;
5. Fee Transmittal (1 pg.);
6. Check - \$180.00;
7. Return Receipt Postcard;

is on the date shown below being:

MAILING

☒ deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22202

Date: Jan 23, 2004

FACSIMILE

transmitted by facsimile to the Patent and Trademark Office.

Nicole M. Gignac  
Signature

Nicole M. Gignac  
(type or print name of person certifying)